



DEPARTMENT OF HEALTH & HUMAN SERVICES

676

Public Health Service

Stacy
2/27/97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 29, 1997

WARNING LETTER
97-DT-12

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

Ronald Roller, President
American Soy Products, Inc.
1474 North Woodland Drive
Saline, MI 48176

Dear Mr. Roller:

An inspection of your soy beverage and fruit-vegetable beverage processing operations was conducted by Investigator Michael V. Owens on February 18 through 25, 1997.

Copies of labels for your food products were collected for review during the inspection. We have now reviewed those labels and FDA has determined that some are in serious violation of the Federal Food, Drug, and Cosmetic Act (Act) and Title 21, Code of Federal Regulations Part 101 - Food Labeling (21 CFR 101), as explained below.

EDENSOY EXTRA

The product is misbranded within the meaning of section 403(r)(1)(A) of the Act, in that it bears the nutrient content claim "great source of vitamins B-12, E, A, D, folic acid, thiamin (B1), protein, phosphorus, magnesium, potassium and calcium" which has not been authorized by FDA.

The product is misbranded within the meaning of section 403(r)(2)(B) of the Act, in that the label bears a nutrient content claim "Extra" and "Fortified with..." but fails to bear a referral statement in accordance with 21 CFR 101.13(g), e.g., "See _____ for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located.

EDENBLEND Rice & Soy BEVERAGE

The product is misbranded within the meaning of section 403(r)(1)(A) of the Act in that it bears the nutrient content claim "A low sodium, cholesterol free food with... carbohydrates, vitamins and minerals" which characterizes the level of carbohydrates in this food, and subjects the product

to the requirements of 21 CFR 101.54(c) (nutrient content claims for good source) for the vitamins and minerals declared on the label.

FDA has not authorized a nutrient content claim for total carbohydrates. In addition, the product as currently formulated does not qualify as a good source for any of the vitamins declared on the label, or for the minerals; calcium, iron, or zinc, based on the declared levels of these nutrients which are less than the required 10% of the RDI per 8 fluid ounces.

This is not intended to be an all-inclusive list of deviations which may be present at your firm. It is your responsibility to assure that all of your firm's products comply with the requirements of the Act and its implementing regulations.

You should take prompt action to correct these violations. Failure to make prompt corrections may result in regulatory action, such as seizure or injunction, without further notice.

During the inspection, we also noted the following with regard to your operations:

1. The firm failed to record carton speed during the production of soy beverages on 7/5/96, 9/2/96, 11/29/96 and 12/26/96 in accordance with 21 CFR 113.40(g)(2)(ii)(c).
2. The firm did not accurately record pre-sterilization temperatures on 12/26/96, 2/3/97, 2/7/97 and 2/12/97 in accordance with 21 CFR 113.40(g)(2)(ii)(a).
3. The firm did not record aseptic surge tank air pressure in a manner which would ensure that the pressures were as specified in the scheduled process in accordance with 21 CFR 113.40(g)(1)(ii)(d).
4. The firm did not file a scheduled process for their apple carrot blend beverage in 8.45 oz. paperboard containers in accordance with 21 CFR 108.25(C)(2). Based on the information provided, VRUIT brand APPLE CARROT BLEND beverage is an acidified low acid canned

food and we consider this product to be an Acidified Food subject to the requirements of 21 CFR parts 108 and 114.

With respect to VRUIT brand Fruit & Vegetable Beverages, the declaration of all juices followed by the parenthetical declaration of "water and juice concentrates" is not the correct way to declare these ingredients. Each concentrated juice must be declared as such in the ingredient statement (e.g., concentrated apple juice) and the water ingredient must be declared in order of its predominance by weight. Also, we question the appropriateness of the term "pure" as part of the % juice statement for these beverages that contain non-juice ingredients such as natural flavors, vitamin C, beta carotene, and calcium carbonate.

Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps you have taken or intend to take to correct these deviations and to prevent the recurrence of similar violations. Your response should be directed to Sandra Williams, Compliance Officer.

Sincerely yours,

John P. Dempster
for Raymond V. Mlecko
Acting District Director
Detroit District

cc via certified mail:

Mr. James Fox
Vice President of Operations